DEPARTMENT OF DEFENSE
ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

ASBPO (40-2b)

BPL 01-07
09 August 2001

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Revision of Donor Deferral Criteria for variant Creutzfeldt-Jakob Disease (vCJD)

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to coordinate the blood programs of the Military Services and the Unified Commands. In that respect, the ASBPO is issuing Blood Program Letter (BPL) 01-07 notifying the Services of the revised policy regarding the donor deferral criteria for vCJD. This policy revises paragraph 4 and 7 of ASBPO BPL 99-09 and question #31 and #32 of the allogeneic donor medical history questionnaire provided in ASBPO BPL 2000-03.

2. The transmissibility of vCJD by human blood or blood products is unknown, and laboratory and epidemiological studies are underway to evaluate the risk. Until such studies are complete, there remains a theoretical risk that vCJD could be transmitted via transfusion. There have been no known cases of vCJD being spread through human blood or blood products to date. In response to the increased incidence of Bovine Spongiform Encephalopathy (BSE) and vCJD in many European countries, the Food and Drug Administration (FDA) is publishing draft deferral criteria for individuals who may have been exposed to the agent for vCJD (enclosure 1). The American Red Cross (ARC) has announced it is expanding the donor deferral criteria recommended by the FDA (enclosure 2). The ASD (HA) has evaluated the two deferral schemes and published policy memorandum entitled " DoD Policy on Blood Donor Deferral Criteria for variant Creutzfeldt-Jakob Disease" dated 09 August 2001 indicating it is in the best interests of the DoD to adopt the deferral criteria, with minor modifications, promulgated by the FDA.

3. With the implementation of this DoD policy, the deferral of donors for possible exposure to the agent for vCJD will be changed to:

a) Anyone who resided in or traveled to the United Kingdom (UK) for a cumulative period of 3 months or more from 1980 through the end 1996 will be indefinitely deferred. In addition:

b) DoD affiliated personnel who resided in or traveled to countries with a risk of BSE (enclosure 3) for a cumulative period of 6 months or more from 1980 through the end of 1996 will be indefinitely deferred.

c) DoD affiliated personnel who resided in or traveled to countries with a risk of BSE (enclosure 3) for a period of 5 years or more after January 1, 1997 will be indefinitely deferred.

d) Others who resided in or traveled to countries with a risk of BSE (enclosure 3) for a period of 5 years or more since 1980 to present will be indefinitely deferred.

e) Anyone having received a transfusion of blood or blood products collected in the United Kingdom since 1980 to present will be indefinitely deferred.

f) Anyone having received bovine insulin prepared in the UK since 1980 to present will be indefinitely deferred.

Note: The FDA draft guidance document makes a distinction between DoD personnel stationed North and South of the Alps between 1980 and 1996. For ease of implementation, the Services in coordination with ASBPO, have determined that no distinction will be made between DoD personnel stationed North or South of the Alps for the period of 1980 through 1996.

4. Question number 31 on DD Form 572 (TEST), August 1998, must be changed to read, "Have you been outside the US or Canada since 1980?" Question number 32 must be changed to read "Have you received a blood transfusion in the UK since 1980?" The Defense Blood Standard System (DBSS) Program Office will update the DBSS software to include these revised questions and develop the appropriate deferral code(s). This update will be available on the DBSS website at http://citpo.ha.osd.mil/projects/dbss/dbss-initiatives.htm. ASBPO will post an updated MS-Word file with the revised DD Form 572 (Test), August 1998, questions to the ASBPO website at http://www.tricare.osd.mil/asbpo/. The U.S. Army Center for Health Promotion & Preventive Medicine (USACHPPM) will develop informational materials regarding health risk for distribution to deferred donors and members of DoD. Donors who desire questions and answers about BSE/vCJD and blood donation may be directed the USACHPPM website at http://chppm-www.apgea.army.mil/MadCowDisease/QA-BSE-vCJD-BD.asp.

5. If a donor is found to have CJD, vCJD, risk factors for CJD or if withdrawal is recommended in cases under investigation for vCJD, the blood donor center must identify blood components prepared from prior collections from that donor. The search of records to identify prior collections from that donor must extend back no less than ten years, and indefinitely to the extent that computerized electronic records are available. Following identification of prior collections, all in-date blood components previously collected from these donors must be retrieved, quarantined and destroyed. Within one week, all consignees must be notified in writing to retrieve, quarantine, and destroy all in-date blood components intended for use in transfusion.

6. Consignee notification will enable the consignee to inform the physician or other qualified personnel responsible for the care of the recipient so that recipient tracing and medically appropriate notification and counseling may be performed at the discretion of health care providers. In cases of donors diagnosed with vCJD or donors under investigation for vCJD, blood donor centers must inform consignees of affected plasma derivatives as well as blood components.

NOTE: DoD does not recommend consignee notification for the purpose of tracing and notifying prior recipients, if a donor has a history of CJD in only one family member or if

a donor is found to have risk factors for vCJD due to geographic risk deferral, transfusion in the UK since 1980, or due to injection of bovine insulin. DoD recommends consignee notification only for the purpose of quarantine and disposition of in-date blood components in these circumstances.

7. This revised donor deferral criteria and changes to Standard Operating Procedures (SOPs) must be implemented by all blood donor centers by 14 September 2001. Each Service Blood Program Officer (SBPO) should complete and fax the attached acknowledgement form (Enclosure 4) to this office within 30 days of receipt of this BPL. A copy of all Service implementing dates and documents must be provided to this office within 90 days from the date of this BPL. The Services must notify the Food and Drug Administration (FDA) of all SOP changes or updates for inclusion into their FDA Blood Establishment License file.

8. Major Ronny Alford is the ASBPO point of contact for this action and can be reached at DSN 761-8010, commercial (703) 681-8010 or via e-mail at ronny.alford@otsg.amedd.army.mil.

Encls

G. Michael Fitzpatrick
G. MICHAEL FITZPATRICK
COL, MS, USA
Director

DISTRIBUTION:
HQDA (DASG-ZA)
CNO N931
HQ USAF/SG

CF:
ODASD (HOP)
ODASD (C&PP)
JS, J4-MRD
HQ USJFCOM/JO2M
HQ USEUCOM/ECMD
HQUSPACOM/J07
HQ USSOUTHCOM/SCSG
HQ USCENTCOM/CCSG
DIR USPACOM JBPO
SBPO USAF
SBPO USA
SBPO USN

Air Force Medical Consultant
Army Medical Consultant
Navy Medical Consultant
DVA Pathology and Laboratory Consultant

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

AUG 9 2001

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: DoD Policy on Blood Donor Deferral Criteria for variant Creutzfeldt-Jakob Disease

In accordance with DoD Directive 6000.12, "Health Services Operations and Readiness," April 29, 1996, this DoD policy establishes blood donor deferral criteria relative to variant Creutzfeldt-Jakob Disease (vCJD).

In response to the increased incidence of Bovine Spongiform Encephalopathy (BSE) and vCJD in many European countries, the Food and Drug Administration (FDA) is publishing draft guidance for deferring individuals who may have been exposed to the agent for vCJD. The FDA deferral criteria are:

(a) Cumulative travel to or residency in the United Kingdom from 1980 to 1996 for $\geq$ 3 months;
(b) DoD personnel stationed in Europe from 1980 to 1990 North of the Alps for a cumulative period of $\geq$ 6 months;
(c) DoD personnel stationed in Europe from 1980 to 1996 South of the Alps for a cumulative period of $\geq$ 6 months;
(d) Any traveler to, or resident of, Europe from 1980 to present for a cumulative period of 5 years (applies to DoD personnel after January 1, 1997);
(e) Anyone having received a transfusion of blood or blood products in the United Kingdom since 1980;
(f) Anyone having taken bovine insulin produced in the United Kingdom since 1980.

The American Red Cross (ARC) has announced that it will begin indefinitely deferring donors who have resided in or traveled to Europe for a cumulative period of 6 months or more since 1980 and donors who have resided in or traveled to the United Kingdom for a cumulative period of 3 months or more since 1980.

I have carefully evaluated, in conjunction with the Service Surgeons General and the Director of the Armed Services Blood Program Office, the two deferral policies and determined that it is in the best interest of the DoD to adopt the deferral criteria recommended by the FDA. I agree with the FDA that, in weighing the theoretical increased risk of the FDA policy against the more significant adverse impact on the blood supply under the ARC policy, the balance in the public health interest for those served by the Military Health System favors the FDA policy. For ease of implementation, the Services, in coordination with the Armed Services Blood Program Office, have determined that it is in the best interests of quality assurance to combine the deferral periods for personnel stationed either North or South of the Alps for the period 1980 – 1996.

The transmissibility of vCJD by human blood or blood products is unknown, and laboratory and epidemiological studies are underway to evaluate the risk. Until such studies are complete, there remains a theoretical risk that vCJD could be transmitted via transfusion. To date, there are no known cases of vCJD having been spread through human blood or blood products. This deferral policy is being implemented to ensure the safety of the blood supply. As more information becomes available, this policy will be reviewed and updated. The DoD deferral for possible exposure to the agent for vCJD will be changed to:

(a) Anyone who resided in or traveled to the United Kingdom for a cumulative period of 3 months or more from 1980 through the end of 1996 will be indefinitely deferred; in addition:

(b) DoD affiliated personnel that resided in or traveled to countries with a risk of BSE for a cumulative period of 6 months or more from 1980 through the end of 1996 will be indefinitely deferred;

(c) DoD affiliated personnel who resided in or traveled to countries with a risk of BSE for a period of 5 years or more after January 1, 1997;

(d) Others who resided in or traveled to countries with a risk of BSE for a period of 5 years or more since 1980 to present will be indefinitely deferred.

(e) Anyone having received a transfusion of blood or blood products collected in the United Kingdom since 1980 to present will be indefinitely deferred;

(f) Anyone having received bovine insulin prepared in the United Kingdom since 1980 to present will be indefinitely deferred.

The ASBPO will include a specific list of the countries with a risk of BSE (primarily Europe) with forthcoming implementation instructions.

Since it is likely that some civilian blood collection agencies will implement slightly different rules regarding donor deferrals, DoD personnel may find themselves deferred by one agency while being accepted by another. Every effort will be made to ensure that DoD personnel understand that the deferrals are purely precautionary, as the vCJD agent has not been demonstrated to be transmissible via transfusion. Steps shall be taken to notify all appropriate commands of these guidelines and to incorporate them into respective Military Department and, where necessary, unified command blood program regulations. The ASBPO shall issue specific implementation instructions to the Military Services through the Service Surgeons General.

This policy will be implemented by all blood donor centers on September 14, 2001. The point of contact for this matter is Colonel G. Michael Fitzpatrick, Director, Armed Services Blood Program Office, at DSN 761-8024, commercial (703) 681-8024, or e-mail at glen.fitzpatrick@otsg.amedd.army.mil.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

cc:
Service Surgeons General
Director, Armed Services Blood Program Office

DRAFT FDA DONOR DEFERRAL CRITERIA

Food and Drug Administration draft guidance for deferring individuals who may have been exposed to the agent for vCJD:

a) Cumulative travel to or residency in the UK from 1980 –1996 ≥ 3 months;

b) DoD personnel stationed in Europe from 1980 to 1990 North of the Alps for a cumulative period ≥ 6 months;

c) DoD personnel stationed in Europe from 1980 to 1996 South of the Alps for a cumulative period ≥ 6 months;

d) Any traveler to or resident of Europe from 1980 to present for a cumulative period of 5 years (applies to DoD personnel after January 1, 1997);

e) Anyone having received a transfusion in the United Kingdom since 1980.

ARC DONOR DEFERRAL CRITERIA

American Red Cross policy for deferring individuals who may have been exposed to the agent for vCJD:

a) Travel or residency to the United Kingdom (UK) for a cumulative period of 3 months or more since 1980;

b) Anyone having a transfusion in the UK, 1980 to present;

c) Travel or residency to Europe for a cumulative period of 6 months or more since 1980.

ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3248
703-681-8024/8025

ACKNOWLEDGMENT OF RECEIPT AND IMPLEMENTATION

BPL 01-07

Revision of Donor Deferral Criteria Pertaining to vCJD

07 August 01

The document listed above was received and the policy implemented by:

SERVICE/UNIFIED COMMAND: _____

DATE RECEIVED: _____

DATE IMPLEMENTED/OR: _____
PROJECTED IMPLEMENTATION

SIGNATURE: _____

NAME/TITLE: _____

Copy this Acknowledgment of Receipt and Implementation and retain one copy in your file. Return the original or an electronic copy to the Armed Services Blood Program Office.

For ASBPO use only

Date Returned: _____

COUNTRIES ASSOSCIATED WITH A RISK FOR BSE			
United Kingdom	**Eastern Europe**	**Western Europe**	**Middle East**
Channel Islands	Albania	Andorra	Oman
England	Belarus	Austria	Turkey
Falkland Islands	Bosnia/Herzegovina	Azores (Portugal)	
Gibraltar	Bulgaria	Belgium	
Isle of Man	Croatia	Denmark	
Northern Ireland	Czech Republic	Faroe Island (Denmark)	
Scotland	Estonia	Finland	
Wales	Hungary	France	
	Latvia	Germany	
	Lithuania	Greece	
	Macedonia	Greenland	
	Poland	Iceland	
	Republic of Moldova	Italy	
	Romania	Liechtenstein	
	Slovak Republic (Slovakia)	Luxembourg	
	Slovenia	Madeira Islands (Portugal)	
	Ukraine	Malta	
	Yugoslavia (Federal Republic includes Kosovo, Montenegro and Serbia)	Monaco	
		Netherlands	
		Norway	
		Portugal	
		Republic of Ireland	
		San Marino	
		Spain	
		Svalbard (Norway)	
		Switzerland	
		Sweden	
		Vatican City	